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Original Article

Anaesthesia Section

Spinal Anaesthesia Success: An Observational Study Assessing Subjective Sensations during Spinal Anaesthetic Drug Injection

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ABSTRACT

Introduction: Spinal Anaesthesia (SA) has stood as the most favoured and dependable technique in regional anaesthesia for the past century. However, despite its widespread use, there are instances of occasional SA failure. Currently, there is no straightforward, cost-effective, and easily administered real-time test-aside from the positive aspiration of Cerebrospinal Fluid (CSF)-that can reliably confirm the deposition of local anaesthetic in the subarachnoid space.

Aim: To evaluate the predictive value of subjective sensations (warmth/tingling/numbness) during the administration of SA for enhancing success rates.

Materials and Methods: A prospective observational study preceeded the recruitment of 500 patients for this investigation. Following the confirmation of CSF aspiration upon injecting the SA drug, Bupivacaine, patients were queried about the sensations of warmth and/or tingling numbness in the lower limb, saddle part, and inner thighs. This assessment was conducted at 30 seconds and one minute after injection. Additionally, patients were asked to report any increase in the area and/or intensity of these sensations. The adequacy of SA was determined by achieving a sensory block upto the desired dermatome level and reaching a Bromage scale score of IV. Evaluations were performed at two minutes, five minutes, 10 minutes, and 15 minutes from the initiation of SA.

Results: The population, predominantly ASA Class-I (60%) and II (40%), exhibited a median age of 45 years, with 54% being male. Intraoperative vital signs, including Heart Rate (HR), Systolic Blood Pressures (SBP), and Diastolic Blood Pressures (DBP), showed a consistent declining trend post-SA administration. Efficacy assessments revealed that Bromage Grade-IV was achieved in 99% of patients at 15 minutes. Notably, subjective sensations of warmth, tingling, and/or numbness proved to be robust predictors of successful SA, with a 218-fold increased likelihood. The diagnostic model demonstrated a high sensitivity of 98%, specificity of 85%, and a Positive Predictive Value (PPV) exceeding 99%.

Conclusion: This study highlights the crucial role of warmth, tingling, and numbness as reliable indicators for successful SA, supported by a robust 97% success rate. Incorporating these patient-reported sensations in assessments provides a practical and accessible approach to improve the efficacy of SA procedures.

Keywords: Cerebrospinal fluid, Failed spinal, Numbness, Tingling, Warmth

INTRODUCTION

The SA, also known as a subarachnoid block, represents a neuraxial, central regional block characterised by a transient sensory, motor, and sympathetic block. This effect is achieved through the injection of a local anaesthetic drug and/or an additive agent into the subarachnoid space [1]. The mechanism involves the blockade of nerve roots within the subarachnoid space [2]. Widely employed for over a century, SA is not only applicable to lower abdominal surgeries but also finds utility in lower limb procedures. Recognised for its speed, simplicity, and reliability, SA stands as a prominent technique in regional anaesthesia [1,2]. In comparison to other regional blocks like epidural anaesthesia and combined spinal epidural anaesthesia, the single-shot SA method is the predominant choice for both elective and emergency surgeries [3]. This technique necessitates minimal instruments and drugs while delivering a superior block quality, associated with low mortality (1:501) [4]. The procedure involves precise placement of the spinal needle tip in the subarachnoid space, confirmation through the aspiration of clear, free-flowing CSF, and subsequent injection of the calculated dose of the local anaesthetic drug into the CSF, ensuring its rapid diffusion to nerve roots at multiple levels.

Despite being the most preferred and reliable technique in regional anaesthesia, instances of occasional SA failure have been documented [4]. SA failure is defined as a partial or incomplete spinal block within 15-20 minutes after injection, requiring supplemental analgesia or conversion to general anaesthesia [5,6]. In 1922, Gaston Lambat, the father of modern regional anaesthesia, asserted that "Two conditions are absolutely necessary to produce SA- puncture of the dura mater and subarachnoid injection of an anaesthetic agent" [3]. Failure to achieve these primary goals, due to various reasons, ultimately contributes to failed SA, which can stem from issues in technique, drug administration, or equipment malfunction [3].

Contributors to nerve block procedure failures fall into three main categories: operator-related failures, technique-related failures, and equipment/drug-related failures. Operator-related issues encompass inadequate drug dosage, improper block assessment, positioning errors, communication lapses, and over-reliance on seniority. Technique-related failures involve faulty execution, anatomical challenges, accuracy issues related to obesity, misplaced injectate, and pseudo-puncture incidents. Equipment/drug-related failures include problems like blocked needles, variations in drug potency, chemical changes, administration errors, and drug resistance [3]. These categories serve to identify potential pitfalls in nerve block procedures, enabling targeted improvements and increased patient safety.

Of the aforementioned causes, faulty technique-even in the hands of an experienced Anaesthesiologist-misplaced injections, and pseudo-successful lumbar punctures (misinterpretation of skin infiltration through local anaesthetic or cystic fluid with CSF) are the most common reasons for failed SA. Globally, failed or inadequate SA has been reported in the range of 1-17% in various countries [3,7-9]. In the context of India, reports suggest that failed SA accounts for 5.7%, with only 1.1% converted to general anaesthesia and 3.18% successfully managed with repeated SA [10]. In current practice,

the confirmation of spinal needle entry into the subarachnoid space relies solely on the aspiration of CSF. Unfortunately, there is a lack of simple, cost-effective, and real-time tests to confirm the deposition of local anaesthetic in the subarachnoid space, posing a potential risk of failure. Studies indicate that sympathetic blockage leads to the termination of vasoconstriction tonic activity, resulting in vasodilation, increased skin temperature, and enhanced blood flow in the anaesthetised area across various regional anaesthesia techniques [11].

Research has demonstrated that elevated skin temperature in the upper extremities can indicate a high level of SA and an increased risk of severe hypotension [12,13]. Notably, within 30 seconds, an increase in skin temperature and a sensation of warmth serve as early indicators of successful SA, as affirmed by Gordh T and supported by subsequent authors [14]. Skin temperature assessment emerges as an alternative test for gauging the onset of SA, particularly in individuals unable to cooperate with sensory testing, such as newborns or those who cannot communicate effectively. To enhance the safety profile of SA, it is imperative to focus on reducing the failure rate to below 1%. Accordingly, the present study aims to assess the predictive value of subjective sensations (warmth/tingling/numbness) during the administration of SA using Bupivacaine, with the objective of improving success rates.

MATERIALS AND METHODS

This was the prospective observational study conducted from November 2019 to November 2022. Following written informed consent, 500 participants were enrolled. Approval was obtained from the Institutional Ethical Committee at our institution (REF/2019/08/027838), and the study was registered in the Clinical Trial Registry of India on 05/11/2019 (CTRI/2019/11/021871).

Inclusion criteria: Included participants comprised males and females aged between 18 to 65 years, falling within American Society of Anaesthesiologist (ASA) Grade-I and II physical status, specifically selected for elective lower abdominal and lower limb surgeries.

Exclusion criteria: Exclusion criteria encompassed patients with absolute contraindications to SA, those classified as ASA Grade-III and higher for elective surgeries, individuals with proven sensory neuropathy of any aetiology, and patients unable to comprehend and document any sensation.

Procedure

Bupivacaine, a commonly chosen local anaesthetic for spinal procedures, belongs to the amide group and is valued for its extended duration of action, particularly beneficial for surgeries requiring prolonged postoperative pain relief. So, a pilot study was conducted with 30 participants, where they were assessed for sensitivity and specificity of warmth and/or tingling numbness in lower limbs or saddle part after injecting Bupivacaine, a local anaesthetic drug through a spinal needle. The results obtained had 98% sensitivity and 99% specificity. Based on these observations, the authors conducted further study on 500 patients with study power of 90% and error of 0.05. All 500 participants, after providing consent, received a single-shot SA while seated, adhering to the standard approach involving lumbar puncture in the L3-L4 interspace [15]. This lower lumbar region selection reduces the risk of spinal cord trauma and ensures optimal anaesthetic solution spread. Lumbar puncture, performed under aseptic precautions, utilised BD® Quinke or Whitacre needles of 26 G or 27 G. On positive aspiration of free flow of CSF, the drug was injected in the given stated manner.

The dosage of 1.5 cc (cubic centimeters) of Bupivacaine was determined based on safety considerations and the desired anaesthesia level, with crucial attention to avoiding excessive motor blockade or systemic toxicity. Subsequently, the authors administered the initial 1.5 cc drug and inquired about sensations of warmth and/or tingling numbness in the lower limb or saddle part. After documenting the patient's response within 30 seconds, remaining dose at the end of one minute and again asked about similar sensations, any increase in intensity and/or area of sensations. All patient responses were meticulously documented.

Sensory and motor blocks were assessed using loss of sensation to pinprick and the Bromage scale, respectively. The Bromage scale evaluates the degree of motor blockade during SA, with scores ranging from I to IV (I. Full flexion of knees and feet-no blockade, II. Just able to move knees-partial blockade, III. Able to move the feet only-almost complete blockade, and IV. Unable to move feet or knees-complete blockade) [16]. The block's action was tested and recorded at 2 minutes, 5 minutes, 10 minutes, and 15 minutes from the induction time of SA. Sensory block upto the desired dermatome level and achieving Bromage scale IV were considered indicators of adequate SA.

STATISTICAL ANALYSIS

The data are presented as medians and interquartile ranges for continuous variables, and frequencies and percentages for categorical variables. Logistic regression, coupled with receiver operating curve analysis, was employed to predict successful SA using the subjective sensation of warmth, tingling, or numbness as an explanatory variable. Failed SA was defined as a composite outcome, characterised by anaesthetic action limited to the L5 level or Bromage scores persisting at I or II until 15 minutes; all other cases were considered successful. Linear regression analyses were conducted to assess the explanatory effect of warmth, tingling, or numbness on HR, SBP, and DBP at successive intervals of time. A significance level of $p < 0.05$ was considered statistically significant, and p-values and 95% confidence intervals were adjusted for multiplicity using the Bonferroni correction. All hypotheses were formulated using two-tailed alternatives against each null hypothesis. The analysis was carried out using R software, version 4.2.2 (R Project for Statistical Computing).

RESULTS

A total of 500 patients were enrolled in the study, with 60% falling under ASA Class-I and 40% under ASA Class-II. The median age of the population was 45 years, and males constituted 54% of the participants. Median height, weight, and BMI were recorded at 163 centimeters, 65 Kg, and 24 kg/m^2, respectively. Comprehensive population characteristics are detailed in [Table/Fig-1].

Characteristic	N=500
Age (years)	45 (33-54)
Sex	
Female	232 (46.4%)
Male	268 (53.6%)
Weight (kg)	65 (59-70)
Height (cm)	163 (158-168)
BMI (kg/m^2)	24.03 (22.66-25.78)
ASA status	
1	298 (60)
2	202 (40)

[Table/Fig-1]: Population characteristics.

[Table/Fig-2] illustrates the intraoperatively measured vitals, including the median HR, SBP, and DBP at baseline before the administration of SA and at various time points afterward. The median trends for HR, SBP, and DBP post-spinal administration all exhibit a declining pattern.

Characteristic	N=500
HR (Baseline)	77 (68-86)
HR (2 min)	75 (66-82)
HR (5 min)	70 (62-78)
HR (10 min)	66 (60-72)
HR (15 min)	65 (60-70)
HR (20 min)	64 (60-68)
HR (25 min)	65 (62-68)
HR (30 min)	65 (63-68)
SBP (Baseline)	123 (118-132)
SBP (2 min)	120 (112-128)
SBP (5 min)	116 (108-120)
SBP (10 min)	110 (103-116)
SBP (15 min)	106 (102-112)
SBP (20 min)	105 (100-110)
SBP (25 min)	106 (103-110)
SBP (30 min)	110 (109-114)
DBP (Baseline)	76 (70-81)
DBP (2 min)	70 (66-78)
DBP (5 min)	64 (60-70)
DBP (10 min)	62 (59-68)
DBP (15 min)	62 (60-65)
DBP (20 min)	64 (60-67)
DBP (25 min)	65 (62-67)
DBP (30 min)	68 (67-70)

[Table/Fig-2]: Intraoperatively measures vitals.
HR: Heart rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure

The efficacy of SA is outlined in [Table/Fig-3]. At two minutes post-SA administration, 9.8% exhibited Bromage Grade-III, 0% were Bromage Grade-IV, 45% presented with a sensory level at L1, and 38% reported a sensory level at T12. By five minutes, 47.8% were Grade-III, 46% were Grade-IV, 28% had a sensory level at T12, and 49% reported a sensory level at T10. These numbers increased to 95% and 99% with Bromage Grade-IV at 10 and 15 minutes, respectively, with 55% experiencing a sensory level at T8 and 33% at T6 at 10 minutes.

Thirty seconds post-spinal administration, 95% of patients reported warmth and numbness, increasing to 98% at one minute. Overall, SA

Characteristic	N=500
Bromage (2 min)	
I	87 (17)
II	364 (73)
III	49 (9.8)
Bromage (5 min)	
I	9 (1.8)
II	24 (4.8)
III	238 (47.8)
IV	229 (46)
Bromage (10 Min)	
I	7 (1.4)
II	4 (0.8)
III	12 (2.4)
IV	477 (95)
Bromage (15 Min)	
I	1 (0.2)
II	1 (0.2)
III	2 (0.4)
IV	496 (99)
Sensory level (2 min)	
L1	226 (45)
L3	23 (4.6)
L5	52 (10)
None	6 (1.2)
T10	4 (0.8)
T12	189 (38)
Sensory level (5 min)	
L1	29 (5.8)
L2	1 (0.2)
L3	1 (0.2)
L5	4 (0.8)
None	6 (1.2)
T10	247 (49)
T12	142 (28)
T7	3 (0.6)
T8	67 (13)
Sensory level (10 min)	
L2	1 (0.2)
L5	4 (0.8)
None	5 (1.0)
T10	36 (7.2)
T12	5 (1.0)
T6	166 (33)
T7	10 (2.0)
T8	273 (55)
Sensory level (15 min)	
L2	468 (94)
L5	1 (0.2)
None	2 (0.4)
T10	1 (0.2)
T12	1 (0.2)
T6	14 (2.8)
T8	13 (2.6)
Warmth/Numbness (30 sec)	477 (95)
Warmth/Numbness (1 min)	489 (98)
Area increased (1 min	468 (94)
Outcome	487 (97)

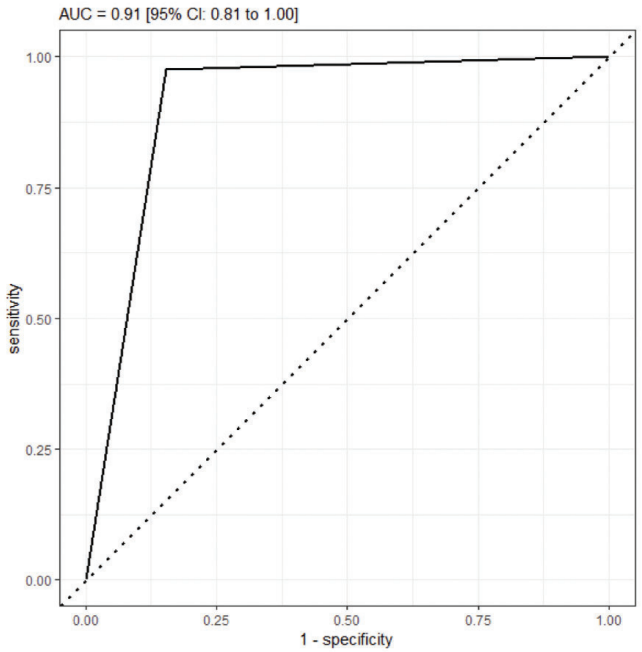
[Table/Fig-3]: Efficacy of Spinal Anaesthesia (SA).

was deemed successful in 97% of patients. The model diagnostics for predicting successful SA with sensations of warmth, tingling, and/or numbness are presented in [Table/Fig-4]. Patients reporting sensations of warmth, tingling, and/or numbness were found to be 218 times more likely to achieve successful SA compared to those who did not experience these sensations (OR: 218, 95% CI: 51.8 to 1514, p<0.001). This diagnostic test exhibited a sensitivity of 98%, a specificity of 85%, a Negative Predictive Value (NPV) of 48%, and a PPV exceeding 99%. The Receiver Operating Characteristic (ROC)

Parameter	Value	95% CI1
Area under the curve	91.08%	80.85% to 100%
Sensitivity	97.54%	95.89% to 98.77%
Specificity	84.62%	61.54% to 100%
Negative predictive value	47.83%	34.48% to 65%
Positive predictive value	99.58%	98.96% to 100%

[Table/Fig-4]: Model diagnostics for predicting successful Spinal Anaesthesia (SA) with sensations of warmth, tingling, and/or numbness.
CI1: Confidence interval

curve for predicting successful SA using subjective sensations of warmth, tingling, and/or numbness is depicted in [Table/Fig-5]. The prediction of vital signs based on sensations of warmth is detailed in [Table/Fig-6]. Overall, the subjective sensations of warmth, tingling, and/or numbness did not exhibit statistically significant effects in predicting intraoperatively monitored vitals.



[Table/Fig-5]: Receiver Operating Characteristic (ROC) curve for predicting successful spinal using subjective sensations of warmth, tingling, and/or numbness.

Outcome	Beta	95% CI1	p-value
HR (2 min)	-0.77	-4.9 to 3.4	0.72
HR (5 min)	-1.0	-5.0 to 2.9	0.61
HR (10 min)	-1.8	-5.3 to 1.8	0.33
HR (15 min)	-1.6	-4.4 to 1.3	0.27
HR (20 min)	-1.6	-4.2 to 1.0	0.24
HR (25 min)	-1.3	-3.7 to 1.2	0.31
HR (30 min)	-1.1	-3.4 to 1.3	0.37
SBP (2 min)	2.4	-1.6 to 6.4	0.23
SBP (5 min)	1.9	-1.9 to 5.8	0.33
SBP (10 min)	1.7	-1.8 to 5.2	0.34
SBP (15 min)	1.3	-1.9 to 4.4	0.43
SBP (20 min)	-42	-60 to -23	<0.001
SBP (25 min)	1.0	-1.7 to 3.7	0.45
SBP (30 min)	0.36	-2.1 to 2.8	0.77
DBP (2 min)	2.5	-0.57 to 5.6	0.11
DBP (5 min)	1.5	-1.3 to 4.4	0.29
DBP (10 min)	1.8	-0.84 to 4.5	0.18
DBP (15 min)	0.84	-1.3 to 3.0	0.45
DBP (20 min)	0.13	-1.9 to 2.2	0.90
DBP (25 min)	0.33	-1.5 to 2.2	0.72
DBP (30 min)	-0.12	-2.4 to 2.1	0.92

[Table/Fig-6]: Predicting vitals monitored post-Spinal Anaesthesia (SA).
CI1: Confidence interval; N=500 participants

DISCUSSION

The SA, introduced by August Bier in 1898 through his experiment on the "cocainisation of the spinal cord" [17], has evolved into a widely adopted regional anaesthesia technique, becoming the preferred choice for various surgeries, including caesarean sections, lower limb procedures, and diverse urological and general surgeries. In this method, a local anaesthetic drug is injected into the subarachnoid space following the aspiration of free, clear, and adequate CSF flow-currently the sole confirmatory test used. Even in expert hands, the failed spinal rate, indicating no effect after successful dural puncture, can reach upto 4%. Recognising the need for a real-time confirmatory test to ensure the appropriate deposition of local anaesthetic drugs in the subarachnoid space, we turned to the phenomenon reported by Milwidsky H and De Vries A in 1948 [18]. They noted that an increase in skin temperature in the upper extremities could signify a high level of SA and an elevated risk of severe hypotension.

Gordh T further emphasised this concept by describing a rise in skin temperature and a sensation of warmth within 30 seconds of initiating spinal drug injection as the initial signs of successful SA. The speculated mechanism underlying this phenomenon is the direct chemical or pharmacological stimulation of afferent thermal fibers by the local anaesthetic. The present study corroborates these findings through subjective assessments [14].

The initial sensation of tingling and numbness in the medial thigh, feet, and perianal region, induced by the uptake of local anaesthetic injected into the CSF via unmyelinated 'C' fibers, has been documented in previous studies [12,13,19]. Penno A et al., investigated the predictive value of skin temperature, noting a 95% predictive value for a temperature rise of 0.35ºC at the feet and 100% for a rise of 1%, requiring a duration of five minutes [20]. In the present study, 477 out of 500 patients reported warmth/numbness at the end of 30 seconds during injection of the local anaesthetic drug, and 489 out of 500 patients experienced warmth/numbness at the end of one minute. Additionally, the area of sensation of warmth/numbness increased in 468 patients until one minute. In this study, subjective assessment test for warmth/numbness demonstrated a sensitivity of 97.54%, specificity of 86.4%, and a PPV of 99.58%. This high sensitivity makes this test a valuable tool to predict the success rate of SA, complementing the gold standard-aspiration of free, clear, and adequate flow of CSF.

Another study defined SA failure as no block after successful dural puncture, reporting a failure rate of up to 3.8% by this definition [21]. The present study results align with this definition, indicating that injecting the local anaesthetic drug Bupivacaine over one minute did not adversely affect the achieved block height, which was confirmed to be T6-T10 with Bromage scale IV at 15 minutes [19]. The authors here observed a decrease in HR, SBP, and DBP until 15 minutes.

Based on these findings, the authors proposed the next phase of this study, wherein it was planned to readjust the spinal needle and drug syringe connection and re-evaluated the free flow of CSF if there is no positive response regarding warmth, tingling or numbness by the patient before injecting the remaining anaesthetic drug. This adjustment aims to prevent inadvertent injections into the subdural or epidural space or an arachnoid cyst, ultimately contributing to a reduction in the overall failed SA rate.

Limitation(s)

The authors here exclusively utilised Bupivacaine as the anaesthetic drug, as this is the most commonly used drug in spinal anaesthesia, and extending these findings to other drugs such as Ropivacaine or Levobupivacaine warrants further investigation. Additionally, the test presented in this study does not predict the achieved block height. The reliance on patient cooperation is a notable limitation, as non-cooperative patients may not provide accurate subjective assessments. Furthermore, the test cannot be reliably applied to patients with peripheral neuropathies, introducing a constraint in its broader applicability.

CONCLUSION(S)

This study introduces a promising method for assessing successful SA based on subjective sensations of warmth, tingling, and

numbness induced by Bupivacaine injection. With a high sensitivity of 97.54%, this test emerges as a valuable predictor, complementing the conventional CSF aspiration gold standard. Demonstrating alignment with established literature and a 97% success rate, this test proves to be the only real time predictor of appropriate deposition anaesthetic drug into the CSF. Future investigations exploring alternative anaesthetics and refining procedural aspects hold potential for enhancing SA success rates and reducing failures.

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